K113642

FEB - 6 2012

PERIMETER® Interbody Fusion Device
510(k) Summary
December 5, 2011

I. Company: Medtronic Sofamor Danek
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Memphis, TN 38132
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II. Contact: Lauren Kamer
Senior Regulatory Affairs Specialist

III. Proprietary Trade Name: PERIMETER® Interbody Fusion Device

IV. Classification Name: Intervertebral Body Fusion Device (21 CFR 888.3080)

Class: II

Product Code: MAX

V. Product Description

The PERIMETER® Interbody Fusion Device consists of cages of various widths and heights which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft. The PERIMETER® Interbody Device is to be used with supplemental fixation instrumentation.

The device is offered in both Titanium Alloy (Titanium-6Aluminum-4Vanadium ELI) and PEEK (Polyetheretherketone). This interbody device is offered in both sterile and non-sterile forms.

The PERIMETER® Interbody Fusion Device is offered in a variety of sizes ranging from 8mm to 20mm in height, 15 mm to 28mm in length and between 19mm and 38mm in width. An array of lordosis options are provided for this device spanning from 4 degrees to 15 degrees of angulation. Both the PEEK and Titanium Alloy devices are designed with teeth across both the superior and inferior surfaces to allow the implant to grip the superior and inferior end plates, thus providing expulsion resistance. Additionally, the Titanium Alloy version of this device offers lateral windows for visibility of the autogenous bone graft.

The purpose of this submission is to add a new inserter to the PERIMETER® Interbody Fusion Device system and to provide the package insert for this reusable device as well as other instruments for use with PERIMETER® Interbody Fusion Device. Additionally, the package insert for Medtronic's CATALYST® instruments, which can also be used with PERIMETER® Interbody Fusion Device, is provided. The modified design of the subject PERIMETER® Interbody Fusion Device does not affect the device's intended use or alter the device's fundamental scientific technology.

VI. Indications for Use

The PERIMETER® Interbody Fusion Device is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior, lateral and oblique. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

VII. Summary of Technological Characteristics

The purpose of this Special 510(k) submission is to seek clearance to add a new two-piece threaded inserter to the PERIMETER® Interbody Fusion Device system. The design, materials, and fundamental scientific technology of the subject PERIMETER® Interbody Fusion Device are identical to the predicate PERIMETER® Interbody Fusion Device, except for the addition of the subject inserter. The subject inserter is constructed of the same materials and represents the same fundamental scientific technology as the predicate inserter; however, the design consists of a two-piece construction in contrast to the 4-piece construction of the predicate inserter.

VIII. Identification of the Legally Marketed Predicate Device Used to Claim Substantial Equivalence

Documentation was provided which demonstrated that the subject PERIMETER® Interbody Fusion Device system is substantially equivalent to the predicate PERIMETER® Interbody Fusion Device system cleared in K090353 (SE Sept 29, 2009) for the PEEK version, and K111525 (SE Aug 24, 2011) for the Titanium Alloy version. Additionally, CAPSTONE® Spinal System was used as a predicate for this submission since the design of the subject inserter is similar to the two-piece inserter recently cleared as part of CAPSTONE ® Spinal System (K103731, SE July 18, 2011).

IX. Brief Discussion of the Non-Clinical Tests Submitted

The subject and predicate PERIMETER® Interbody Fusion Device devices are identical in terms of indications for use, intended use, performance specifications, and fundamental technological characteristics. Assessment of the instrument modifications has been completed in accordance with Medtronic design control processes. Cleaning and sterilization validations and assessments have been conducted according to the following standards to provide the appropriate disassembly, cleaning, and sterilization instructions for the new inserter, as well as the other instruments for use with PERIMETER® Interbody Fusion Device:

- ISO 17664:2004 , Sterilization of medical devices- Information to be provided by the manufacturer for the processing of resterilizable medical devices

- ANSI/AAMI/ISO 17665-1:2006 , Sterilization of health care products- Moist heat- Part 1: Requirements for development, validation, and routine control of sterilization process for medical devices
- ANSI/AAMI/ISO TIR 17665-2:2009 , Sterilization of health care products- Moist heat- Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1
- AAMI TIR 12:2010 , Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers
- ANSI/AAMI ST79:2010 & A1:2010 , Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- AAMI TIR 30:2003 , A compendium of processes, materials, test methods and acceptance criteria for cleaning reusable medical devices
- ANSI/AAMI ST81:2004 , Sterilization of medical devices - Information to be provided by the manufacturer for the processing of re-sterilizable medical devices

X. Conclusions Drawn from the Non-Clinical Tests

A risk analysis was completed. Based on the risk analysis and additional supporting documentation provided in this premarket notification, Medtronic believes that the subject PERIMETER® Interbody Fusion Device demonstrates substantial equivalence to the predicate PERIMETER® Interbody Fusion Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Medtronic Sofamor Danek USA
% Ms. Lauren E. Kamer
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K113642
Trade/Device Name: PERIMETER® Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: December 09, 2011
Received: December 12, 2011

Dear Ms. Kamer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113642

510(k) Number (if known): _____

Device Name: PERIMETER® Interbody Fusion Device

Indications for Use:
The PERIMETER® Interbody Fusion Device is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior, lateral and oblique. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113642